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DRAFT "RISK ASSESSMENT" DESCRIBED AS GROUNDLESS SPECULATION

Underlying scientific foundation missing

WASHINGTON, D.C. -- In a draft document made public today, the Environmental Protection Agency (EPA) has contributed to the unsupportable and speculative process of ascribing risk where scientific basis is lacking.

Of the 23 published epidemiological studies concerning a possible association between exposure to environmental tobacco smoke (ETS) and the incidence of lung cancer in nonsmokers, only five have reported statistically significant associations. The other 18 studies reported relative risks which were not significantly elevated using 95 percent confidence intervals.

Thus, the ETS risk assessment -- based on the epidemiologic studies -- suffers from a fatal fundamental flaw: it assumes, contrary to fact, that ETS has been shown to be a health hazard. The draft has yet to undergo the serious scientific review, including the scheduled analysis by the EPA's Science Advisory Board. The critical analysis that will be undertaken, should it follow past appraisals of the scientific literature, is likely to significantly undermine the very basis of this draft.

The most recent critical assessment (1990), funded by the U.S. Department of Health and Human Services, failed to conclude that ETS exposure causes nonsmoker lung cancer. Instead the authors reported "verification of the possible association of ETS and lung cancer represents an important challenge to epidemiologists, laboratory scientists, and public health authorities."

Examining the published studies on ETS exposure and lung cancer, the government funded review noted that the studies report weak and inconsistent results and fail to address the many methodological issues that could generate false associations. Methodological flaws discussed included misclassification of smokers as nonsmokers and the questionable validity of ETS exposure estimates. Insight into the difficulty with use of spousal smoking as the exposure measure can be demonstrated by a large U.S. study in which risk reported varied dramatically based on family members interviewed. No increase in risk was reported if exposure to ETS was estimated by the patient or her smoking husband. Only if a son or a daughter -- adults who had not lived with the parents for many years -- were interviewed, was an increase in risk reported.

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Many in the scientific community have argued that there is a very real question as to whether a risk assessment exercise can be justified at all in light of the deficiencies and lack of consistency in the epidemiologic studies.

This very issue was recently addressed by a prestigious panel of scientists at an international symposium on ETS held at McGill University in Montreal, Canada. As the opening presenter to the risk assessment panel at the symposium emphasized:

"The first order of business * * * is for proper studies to be carried out with respect to a possible causal link between ETS and particular diseases. If studies justifying a causal inference were to become available, we could then employ the remaining steps in the risk assessment technique."

Not only do the individual epidemiologic studies fail to support a cause and effect relationship, statistical manipulations of all the studies combined -- like that conducted by the EPA -- result in a set of artificial numbers. As a scientist noted of this process at the McGill Symposium:

"[O]ne cannot add apples and oranges in this fashion -- and indeed, to persist with the metaphor, no number of bad apples will add up to any quantity of good apples."

These calculations are, in fact, orders of magnitude higher than would be found through an extrapolation from active smoking exposure to nonsmoker exposure. For example, if one were to examine the difference in retained particulate matter among smokers and nonsmokers exposed to ETS, then extrapolate a "risk," these estimates would be 20 fold lower than the most conservative epidemiology-based estimates.

As a number of scientists have noted, ascribed risks based on the epidemiology would appear to suggest that ETS has 10-20% or more of the effect of active smoking -- an estimate totally inconsistent with levels of exposure experienced by nonsmokers. This biologically implausible discrepancy casts further doubt on the validity of the epidemiologic evidence.

A review of the literature on the amount of ETS exposure indicates that nonsmokers are exposed to only trace amounts of smoke constituents. Further, experiments measuring tobacco specific components in the air report that in common situations, nonsmokers would have to spend several hundred hours in an indoor environment to be exposed to one "cigarette equivalent."

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The international symposium on ETS held in Canada late last year, also addressed the issue parental smoking and respiratory health in children -- an issue raised by the EPA. The presenter on this issue noted that while the epidemiological studies generally report a statistical association between the presence of a smoker in the home and respiratory incidence (coughing, congestion, infections) among infants less than two years of age, no consistent association has been reported among children older than two years of age or in environments other than the home.

The presenter concluded, however, that "Several factors other than ETS ... alone or in combination with one another, may account for the association between parental smoking and impaired respiratory health in younger children. Among these are socioeconomic status and related factors, and biological mechanisms other than ETS associated with the prenatal and early postnatal period."

Even if one sets aside all of the technical problems and inadequacies in the draft EPA risk assessment, fundamental problems remain in the lack of scientific support from the ETS literature. The statistical manipulations represented by the EPA draft risk assessment constitute, at the very best, groundless speculation.

It is regrettable that the EPA has seen fit to use its limited resources on this exercise, particularly in view of the fear and confusion that undoubtedly will be engendered by the assessment's release.

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